REMARKS

Applicants reserve the right to prosecute non-elected subject matter in subsequent divisional applications.

Amendments to the Specification

Applicants have amended the Specification to respect the proprietary nature of trademarks used in the application by conforming to proper usage conventions. The entry of said amendments is respectfully requested.

Amendments to the Claims

Applicants have amended claims and added new claims to this U.S. National Phase application.

Claim 21 a)-d) has been amended to remove recitation of SEQ ID NO:1, SEQ ID NO:4 and SEQ ID NO:6.

Claim 21 b)-d) have also been amended to remove recitation of SEQ ID NO:3 and SEQ ID NO:5..

Claim 28 a)-b) have been amended to remove recitation of SEQ ID NO:9, SEQ ID NO:12, and SEQ ID NO:14.

Additionally, new claims 34-39 have been added. Support for claims 34-36 can be found in claim 21, as these claims are of narrower scope than claim 21. Support for new claim 36 can be found in claim 26, as new claim 36 is of narrower scope than claim 26. New claims 37-38 are methods of using the polypeptides of claim 21. Support for claims 37-38 can be found throughout the specification, e.g., page 37, line 21 to page 38, line 4. Support for claim 39 can be found throughout the specification, e.g., page 27, line 27 to page 28, line 2.

These amendments are made in order to expedite prosecution and not for reasons related to patentability. The entry of said amendments is respectfully requested.

Response to Restriction Requirement

Applicants reiterate their election to prosecute the claims of Group II with traverse. The propriety of the restriction requirement is traversed for at least the following reasons.

I. The unity of invention standard *must* be applied to the present application

A. The present application is a national stage application

The instant application is a national stage application. In a letter mailed 01/30/2003, the USPTO notified applicants that U.S. Serial No. 09/763,902 was accepted as an application under 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

Section 200 of Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides:

> Non provisional and provisional applications are national applications. Treatment of >a< national *>application< under U.S.C. 111 and >a< national stage **>application (a national application which entered the national stage from an international application after compliance with 35 U.S.C. 371)< are similar but not identical. Note the following examples:
>
> (A) Restriction practice under MPEP § 806+ is applied to national applications under 35 U.S.C. 111(a) while ***unity of invention practice under MPEP Chapter 1800 is applied to national stage applications***. . . .(emphasis added)

Id at page 200-2.

B. Unity of Invention *must* be applied in national stage applications

Section 1850 of the MPEP provides:

> . . . [W]hen the Office considers international applications . . . during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111 . . .
>
> In applying PCT Rule 13.2 to . . . national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary

> examination, claims to the categories which meet the requirements of PCT Rule 13.2 . . .

Id at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

> Examiners are reminded that unity of invention (not restriction) practice is applicable . . . in national stage (filed under 35 U.S.C. 371) applications.

Id at page 1800-149, column 1.

II. Specific provisions of the Administrative Regulations Under the PCT and the corresponding provisions of the MPEP strongly support a finding of unity of invention among all of the claims in the present case

A. Unity of Invention is accepted as between claims 21 and 34 to polypeptide sequences, and claims 22, 23, 34-36 and 28 to the polylnucleotide sequences which encode them

Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT provides that unity of invention is accepted as between claims to polypeptide sequences and claims to polynucleotide sequences encoding those polypeptides. Those Examples are cited in MPEP section 1893.03(d) at page 1800-149, column 2 ("[n]ote also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions . . . ")

Thus, in the present case, unity of invention exists at least as between claims drawn to polypeptide sequences SEQ ID NO:2-3, SEQ ID NO:5 and SEQ ID NO:7-8 (*i.e.,* claims 21 and 34) and as to claims drawn to polynucleotide sequences which encode those polypeptides, sequences SEQ ID NO:10-11, SEQ ID NO:13, SEQ ID NO:15, and SEQ ID NO:16 (*i.e.,* claims 22, 23, 28, 35 and 36).

Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to claims 21-23, 28, and 35-36, and examine those claims in a single application.

B. Unity of invention exists with respect to dependent claims in the same claim category as the independent claim from which they depend

MPEP section 1850(A) and 1893.03(d), which recite the provisions of paragraph (c) of Part 1 (entitled "Instructions Concerning Unity of Invention") of Annex B (entitled "Unity of Invention") to the Administrative Instructions Under the PCT, provides:

> **(A) Independent and Dependent Claims.**
>
> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).
>
> (i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention . . . .

See MPEP section 1850(A) at page 1800-61. See also MPEP Appendix AI at page 53.

In the present case, claims 32 and 34, both of which depend directly or indirectly from claim 21, are directed to compositions of matter, *i.e.,* to products. Both of these claims contain all of the features of the independent claim.

Thus, it is improper to restrict claim 21 from claims 32 and 34 as the Examiner has done. Therefore, Applicants respectfully request that the Examiner reconsider the finality of the Restriction Requirement at least as to the composition of matter claims, claims 21, 32 and 34 and that those claims be considered together in a single application.

Additionally, Applicants remind the Examiner that it is proper and hereby requested, for rejoinder of method of use claims 36, 37, and 38 with claim 21, in compliance with Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in Light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)." Similarly, they request that claims 29-31 and 39 be examined together with claim 28, for the same reasons.

III. Unity of invention exists as between all of Applicants' claims

MPEP 1850 provides:

> Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Id at page 800-61.

MPEP 1893.03(d) similarly provides:

> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

Id at page 1800-149.

In the present case, unity of invention exists among all of Applicants' claims. The claimed polypeptide sequences and the claimed polynucleotide sequences encoding them are corresponding technical features which are common to all of Applicants claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application.

A. The claimed polypeptide sequences, and the claimed polynucleotide sequences encoding those polypeptide sequences, are corresponding technical features that are common to all of Applicants' claims and that serve to technically interrelate them

Applicants' claims recite *inter alia* the polypeptide sequences SEQ ID NO:2-3, SEQ ID NO:5 and SEQ ID NO:7-8, and polynucleotides encoding those polypeptides, which sequences include the polynucleotide sequences SEQ ID NO:10-11, SEQ ID NO:13, and SEQ ID NO:15-16.

See Table 1 of the specification. Applicants respectfully submit that the claimed polypeptide sequences SEQ ID NO:2-3, SEQ ID NO:5 and SEQ ID NO:7-8, and the claimed polynucleotide sequences encoding them, are corresponding technical features, given that the former are encoded by the latter, and conversely, the latter encode the former.

Further, the claimed polypeptide and corresponding polynucleotide sequences are common to all of Applicant's claims, given that each claim refers to one or both either explicitly or implicitly, by virtue of depending from a claim which makes an explicit reference to the claimed sequences.

In particular, Applicants' composition of matter claims (21, 22, 28, 32, and 34-36) are drawn to either the sequences themselves (claim 21, drawn to polypeptide sequences, and claims 22, 28, and 35-36 drawn to polynucleotide sequences), to compositions of matter which comprise the sequences as one element (claim 32, drawn to pharmaceutical compositions; claim 23, drawn to recombinant polynucleotides of claim 22; claim 25, drawn to a transgenic organism comprising the recombinant polynucleotide of claim 23), or to compositions of matter wherein the claimed sequences functionally limit the claimed subject matter (claim 27, drawn to antibodies which specifically bind a polypeptide of claim 21; claim 24, drawn to a cell transformed with the recombinant polynucleotide of claim 23).

IV. Regardless of whether the Unity of Invention standard is applied, a simultaneous search of both the claimed polynucleotides and the claimed polypeptides which they encode would not impose an undue burden on the Examiner

In Applicants' method claims 26, 29-31, 33, and 36-39, the claimed polypeptide and polynucleotide sequences serve as the product of the claimed method, as a reagent for performing the method, or as the target of a claimed screening method.

In particular, claim 26 is drawn to a method of polypeptide production which have as their product any of the polypeptides of claim 21. Similarly, claims 37 and 38 are drawn to screening methods that identify compounds which bind to or modify the activity of, respectively, the same polypeptides, and claim 33 is drawn to a treatment method which employs those polypeptides.

Likewise, claims 29-31 are drawn to methods of detecting any of the polynucleotides of claim 28, and method claim 39 has as its target those polynucleotides.

Therefore, a search of one of the claimed polypeptide or polynucleotide sequences will necessarily reveal art relevant to the corresponding polynucleotide or polypeptide sequence, respectively, as well as art relevant to the related method claims, and examination of all of these claims together would therefore not impose an undue search burden on the Examiner.

Indefiniteness Rejection under 35 U.S.C. §112, second paragraph

As a preliminary matter, Applicants respectfully bring to the Examiner's attention that the instant application is a U.S. National Phase application. Therefore, application of the Unity of Invention standard as cited in the MPEP section 1893.03(d) compels the Examiner to apply the unity of invention in national stage applications as discussed *supra*.

Claims 22 and 26 were rejected for allegedly depending from withdrawn claim 21, as lacking sufficient antecedent basis for the limitation "claim 21" in the language of claims 22 and 26. Applicants believe that said rejection is improper, as the unity of invention standard applies to the instant application as a U.S. National Phase application. Thus, there is proper antecedent basis for the claim language limitation "claim 21" in both claims 22 and 26 when the unity of invention standard is applied. Therefore, withdrawal of this rejection is proper and hereby requested.

Anticipation Rejection under 35 U.S.C. §102 (a)

Claims 22-24, 26 and 28-31 were rejected under 35 U.S.C. §102 (b), allegedly because they were anticipated by Kain et al. (J. Biol. Chem. 273(2):981-988 (1998)). This rejection is respectfully traversed.

Applicants have amended claims 21 and 28 to remove reference to SEQ ID NO:1 and SEQ ID NO:9. Thus, the teachings of Kain et al. are rendered moot to the instant U.S. national phase application. Withdrawal of this rejection under 35 U.S.C. §102 (b) is therefore respectfully requested.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding objections/rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at the number listed below.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

Respectfully submitted,

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